REMARKS

The Office Action mailed June 9, 2009 has been carefully considered. Within the Office Action Claims 1, 3-30, 33 and 34 have been rejected. The Applicants have amended Claims 1, 9, 10, 11, and 23. Reconsideration in view of the following remarks is respectfully requested. An RCE accompanies this reply.

Claim Objection

Within the office action, Claim 11 has been objected to for a minor error. Applicants have amended Claim 11 to overcome the objection. Withdrawal of the objection is respectfully requested.

Rejection under U.S.C. § 103

Claims 1, 4-6, 10, 11, 28, 33 and 34 have been rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,599,272 to Hjertman in view of U.S. Patent No. 5,997,513 to Smith et al. (hereinafter Smith). The Applicants respectfully traverse.

Specifically, the Office Action contends that the elements of Claim 1 are disclosed in Hjertman except that Hjertman does not teach a retaining means configured to selectively lock the needle assembly at a locked position at the through opening. The Office Action further contends that Smith teaches this limitation and that it would be obvious to one having ordinary skill in the art to incorporate Smith into Hjertman in order to reach the claimed subject matter. The Applicants respectfully disagree for the reasons set forth below.

In determining obviousness four factual inquiries must be looked into in regards to determining obviousness. These are determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims in issue; resolving the level of

ordinary skill in the pertinent art; and evaluating evidence of secondary consideration. Graham v. John Deere, 383 U.S. 1 (1966); KSR Int'l Co. v. Teleflex, Inc., No 04-1350 (U.S. Apr. 30, 2007) (" Often, it will be necessary . . . to look into related teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.") (emphasis added).

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983). Thus, when considering the whole prior art reference its entirety, portions that would lead away from the claimed invention must be considered. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983), See M.P.E.P. 2141.02. Thus, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731 (Fed. Cir. 1983).

Hjertman is directed to an injector device for containers having an opening for an injection needle. The container in Hjertman is a syringe type with a barrel of substantially constant axial cross-section. In one embodiment, the devices include a penetration arrangement operable to move the needle from a rear position to a forward position. Hjertman discloses an injection arrangement operable at least to expel container content through the needle, and a transmission and a switch system which allows manual energy applied to the device to manually operate the penetration arrangement and then manually operate the injection arrangement. (Hjertman, Abstract).

Smith discloses a syringe needle protection device utilizing a hollow needle cover which may slide over or within a syringe cylinder. Smith's hollow needle cover has a reduced end capable of receiving and holding or ejecting the needle cap. The device may also include a means for releasable locking onto the needle cap so that the needle cap locks onto the needle cover. While the cap is being replaced the needle cap can be snapped onto the needle cover until the cap is released when the cap is fixed back in place over the needle. A locking mechanisms locks the needle cap to the needle cover and can prevent the needle cap from being removed from the needle cover until the needle cover is fully extended over the needle. The cover allows the needle holder to be unscrewed or broken off when the user is finished with the needle. (Smith, Abstract).

Hjertman and Smith thus describe devices that are fully mechanical and that allow only manual connection of the needle to the medication container. In Hjertman, connecting the needle 223 to the medication container 220 requires manually attaching the support of the needle 223 onto the end of the medication container 220 while the end projects out of the housing 210 (See Hjerman, Figures 2B and 2C; Column 20, lines 39-45).

With regard to Smith, Smith discloses connecting the needle 9 to the medication container in which Smith's device requires manually bringing the needle assembly to the end of the syringe 36 (see Figure 9a) and then manually attaching the support of the needle 9 onto said end (see Smith, Figure 9b; Column 4, lines 1-6 and lines 29-31).

One skilled in the art would not be motivated to combine the two references to reach the claimed subject matter. It has not been established in the Office Action as to how the devices in Hjertman and Smith would be combined by the skilled person to reach Applicants' device. For instance, the needle cover 2 in Smith is slidably mounted on the syringe (see column 3, lines 50-53) and forms with, the syringe, the needle assembly and the needle cap, a full device which is

not intended and not adapted to be incorporated into the mechanism disclosed in Hjertman. In particular, the Office Action fails to explain how the slidable needle cover in Smith would be configured such that the needle cover 2 would be used in Hjertman's device. For at least these reasons, a *prima facie* case of obviousness has not been established.

In addition, the combination of references do not teach or suggest each and every element/limitation in the claims. Neither reference teaches or suggests that the actuator means is electromechanical. (Specification, Page 16, Lines 1-9). Further, neither reference teaches or suggest that the connection of the needle to the medication container is performed automatically. In particular, Applicants' specification states that assembly of needle 25 to cartridge 4 is controlled fully automatically by control unit 6, and is activated by simply inserting needle assembly 32, by the open end of needle housing 31, inside opening 30 in bottom wall 15 of housing 2. (Specification, Page 12, lines 2-8; Page 18, lines 13-27).

Claim 1 recites, *inter alia,* electromechanical actuator means configured to move said medication container within said housing to and from said contact surface; retaining means configured to selectively lock said needle assembly at a locked position at said through opening, wherein said electromechanical actuator means and said retaining means are configured to allow automatic connection of said needle to said medication container by moving said medication container towards said contact surface from a first operating position withdrawn inside said housing to a second operating position while said retaining means maintains said needle assembly at said locked position. As stated above, neither reference teaches or suggests an electromechanical actuator, as recited in Claim 1. Further, neither reference teaches or suggest that the connection of the needle to the medication container is performed automatically, as recited in Claim 1. Considering that the combination of references does not teach or suggest each and every element/limitation in Claim 1, a *prima facie* case of obviousness has not been established. For at least these reasons, Claim 1 is non-obvious over the cited art.

Claims 3-30, and 33-34 have also been rejected in light of several references. However, Claims 3-30, and 33-34 are dependent on Independent Claim 1. As stated above, Claim 1 is allowable over the cited references. Accordingly, Claims 3-30, and 33-34 are allowable for being dependent on an allowable base claim.

Conclusion

It is believed that this reply places the above-identified patent application into condition for allowance. Early favorable consideration of this reply is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. Please charge any additional required fee or credit any overpayment not otherwise paid or credited to our deposit account No. 50-3557. An RCE accompanies this reply.

Respectfully submitted,

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